K012135

WRP Asia Pacific Sdn Bhd
147817V

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AUG 1 2001

510(k) SUMMARY

1.0 Submitter:

Name: WRP Asia Pacific Sdn Bhd
Address: Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA
Phone No.: +60 3 8706 1486
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Date of Summary Prepared: 03 JUL 2001

2.0 Contact Person:

Name: Mr. Yue Wah, CHOW
Phone No.: +60 3 8706 1486
Fax No.: +60 3 8706 1485

3.0 Name of the device:

Trade Name: 1. Profeel
2. Multiple or Customer's Trade Name
Device Name: Powder Free Brown Latex Surgical Gloves, Sterile (Protein Labeling Claim)
Common Name: Surgical Gloves
Classification Name: Surgeon's Gloves (per 21 CFR 878.4460)

4.0 Identification of The Legally Marketed Device:

Class I Powder Free natural rubber latex Surgeon's gloves, 79KGO, that meets all the requirements of ASTM standard D 3577 – 00 Type 1 and FDA 21 CFR 800.20.

5.0 Description of The Device:

The Powder Free Brown Latex Surgical Gloves, Sterile (Protein Labeling Claim) meets all the requirements of ASTM standard D 3577 – 00 and FDA 21 CFR 800.20.

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6.0 Intended Use of the Device:

The Protein Free Brown Latex Surgical Gloves, Sterile (Protein Labeling Claim) is made of natural rubber latex intended to be worn on the hand of healthcare personnel, operating room personnel and similar personnel to prevent contamination between the healthcare or similar personnel and the patient's body, fluids, waste, or environment.

7.0 Summary of The Technological Characteristics of The Device:

The Powder Free Brown Latex Surgical Gloves, Sterile (Protein Labeling Claim) are summarized with the following technological characteristics compared to ASTM or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions	ASTM D 3577 – 00	Meets
Physical Properties	ASTM D 3577 – 00	Meets
Freedom from pinholes	ASTM D 3577 – 00 FDA 21 CFR 800.20	Meets
Powder-Free	ASTM D 6124 - 00	Meets 2 mg/glove maximum
Protein Level	ASTM D 5712 - 95	< 50 µg/g
Biocompatability	Primary Skin Irritation in Rabbits	Passes (Not a primary skin irritant)
	Dermal Sensitization	Passes (Not a contact sensitizer)

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8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above.

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

10.0 Conclusion

It can be concluded that the Powder Free Brown Latex Surgical Gloves, Sterile (Protein Labeling Claim) will perform according to the glove performance standards referenced in section 7 above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, this device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2001

Mr. Yue Wah Chow
Head of Department, QA/Ra
WRP Asia Pacific Sdn. Bhd.
Lot 1, Jalan 3,
Kawasan Perusahaan Bandar Baru
Salak Tinggi, Sepang Selangor
MALAYSIA

Re: K012135
Trade/Device Name: Powder Free Latex Surgical Gloves With Protein Content Labeling Claim (50 Micrograms or Less)
Regulation Number: 878.4460
Regulatory Class: I
Product Code: KGO
Dated: July 3, 2001
Received: July 9, 2001

Dear Mr. Chow:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug

Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

WRP Asia Pacific Sdn Bhd

147817V

INDICATIONS FOR USE

Applicant: WRP Asia Pacific Sdn Bhd

510(k) Number (if known): K012135

Device Name: POWDER FREE BROWN LATEX SURGICAL GLOVES, STERILE (PROTEIN LABELING CLAIM) 50 MICROGRAMS OR LESS

Indications For Use:

The surgeon's glove is a device made of natural rubber latex intended to be worn by surgeons and/or operating room personnel to protect a surgical wound from contamination.

_____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter _____
(Per 21 CFR 801.109)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012135